



Dissemination and implementation of
the new food safety tool for exposure
assessment - Flavourings, Additives and
food Contact materials Exposure Tool
(FACET)

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Executive Summary

On 9 December 2013, on the occasion of the Plastics & Paper in Contact with Foodstuffs (P&P) International conference, the JRC launched a downloadable tool to estimate consumers exposure to food additives, flavourings and food contact materials. The tool, called **FACET** (standing for Flavourings, Additives, and food Contact materials Expose Tool) is a desktop software application, which contains databases of chemical concentrations for flavourings and additives, industry data on retail packaging composition, chemical occurrence data or their prediction, and food consumption diaries. These databases are combined into probabilistic dietary exposure models that estimate exposure in different populations of consumers in the EU.

The FACET tool is a result of a project of the same name, funded under the 7th Framework Programme. The aim of the project which ran from 2008 to 2012 was to significantly reduce the uncertainty in the level of dietary exposure for these classes of substances in the EU population. The JRC was part of the consortium and was designated as responsible entity for the dissemination and sustainability of the tool. Implementation and sustainability are two aspects which are critical in order to ensure 1) the implementation of improved or refined functions to go from a RTD prototype output to a fully functional service and product that can be made available to the stakeholders 2) The dissemination and exploitation of the improved tool for the stakeholders.

The stakeholders have been identified and include the European Food Safety Authority (EFSA), the additives associations (including the European Flavour Association, EFFA), the additives associations (including FoodDrinkEurope, FDE), the FIG association (Facet Industry Group, which comprises more than 10 sectorial associations in the field of food packaging), DG SANCO (all 3 sectors), as well as the member states competent authorities and risk assessment bodies.

During 2013 the JRC coordinated the testing of the prototype software by core users and organised a number of trainings for the industry associations that can use FACET as a screening tool for R&D and innovation. A dedicated 2 day hands-on demonstration was also organised for the Food Ingredient and Packaging (FIP) Unit of the European Food Safety Authority (EFSA) in the context of specific exposure assessment to these categories of substances.

FACET will have added values in two main areas: in the context of exposure assessment, it already allows to reduce the uncertainties for the evaluation for these three specific sectors. Consequently, FACET will constitute a unique tool for post market monitoring since it reflects the real exposure of a targeted population to a food chemical, taking into account the variability of concentration and the real occurrence for each food category. In addition, in the context of innovation, the tool can be used to explore changes in the formulations of flavours, additives or food contact materials which can lead to more effective or more sustainable developments. Importantly, the industry is already familiar with the tool, and their comments on usability have been integrated into the software.

The overall impact of FACET will be evident at a number of levels including protection of the consumer, fostering innovation in the food chain, driving the scientific approach, and influencing international food regulatory affairs through a focused risk assessment approach.

In 2014, further trainings are foreseen. The software and further information is available at: http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food

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Introduction

"You are what you eat," they say. European efforts to better understand the ingredients and handling of food for human consumption are an important safeguard tool in the food production system. Flavours, additives and packaging are a major part of the modern food production chain. Yet, recent years have witnessed an increasing focus on safety of the food chain and have highlighted concerns for consumers with respects to the presence of chemicals in foods. Consequently there has been a need clearly highlighted to offer developments for the improved assessment of exposure to such chemicals across the EU.

The 7th Framework EU funded project Flavourings, Additives and Food Contact materials Exposure Tool, or in short FACET, was an EU project whose scope was to estimate exposure to flavours, additives and food contact materials across Europe. This project ran from September 2008 and lasted for 4 years. Its consortium consisted of 20 collaborative partners across the EU, from industrial, academic and public body research centres and represented 6MM+ R&D. The project also benefited from a unique FACET Industry Group (consortium of packaging industries and associations which also invested 0.5MM in cash and 1.5MM in kind).

The concept behind this project was the creation of a food chemical exposure surveillance system, sustainable beyond the life of the project, which covered representative regions of the EU and which aimed to meet, to the highest possible standards, the needs of the EU regulatory authorities in the protection of consumer health.

The FACET software tool is tailored for assessing dietary exposure to 3 categories of food chemicals in populations of consumers in Europe. It contains databases of chemical concentrations for flavourings and additives, industry data on retail packaging composition, chemical occurrence data or their prediction, and food consumption diaries. These databases are combined in probabilistic dietary exposure models that estimate exposure in different populations of consumers in the EU. FACET was developed with the aim to significantly reduce the uncertainty in the level of dietary exposure for these classes of substances in the EU population.

It presents itself in the form of a desktop software that be downloaded, installed, so that dietary exposure assessments to these three chemical groups can be run on the user's computer.

The Joint Research Centre (JRC), beyond its participation as project partner, was designated as responsible entity for the dissemination and sustainability of the tool. This report represents and summarises the activities carried out in 2013 regarding the post-life dissemination and implementation activities under the management of the JRC.

Achievements of FACET as RTD project

The original concept behind FACET was the creation of a food chemical exposure surveillance system, sustainable beyond the life of the project to meet the needs of EU regulatory authorities in the protection of consumer health. At the outset, there were a number of bottlenecks in exposure assessment. These included access to national food consumption databases, difficulty with food categorization, and limited knowledge on food chemical occurrence, lack of data on food chemical concentration and on packaging substances. FACET was designed to address all of these issues with regard to the specific concerns of flavourings, food additives and food contact materials.

The major achievement of FACET has been the creation of an exposure assessment software system. A validated software for deterministic and probabilistic modelling of food chemical intake has been developed. Additional important developments in the project have included the establishment of a migration modelling framework for packaging materials into foods, the construction of a tiered food intake database with an integrated harmonized food categorization system and the collection of extensive concentration data for additives, flavourings and food packaging migratory compounds. For flavourings, a total of 41 substances were selected. Concentration data were also collected for natural occurrence of the target substances. Furthermore, analytical investigations for certain flavouring substances in foods have been conducted. In relation to food additives, 32 priority additives were established by the additives and industry questionnaires for providing additives usage levels were developed. For food packaging, data collection on the chemical composition of food packaging materials along with information on the extent and conditions of use was undertaken and led to an inventory list of 6,475 substances that are either single substances or are defined or non-defined mixtures of two or more substances. A new in silico QSAR approach was developed, validated and used to evaluate the toxicological significance of exposure to packaging substances. The outcome was presented in a dedicated public conference in October 2012.

Post project life in 2013 and role of JRC

The JRC, beyond its participation as project partner, was designated as responsible entity for the dissemination and sustainability of the tool. This tool is of major impact for JRC since in the inception of the project the partners established that the final product would be under the care and governance of the JRC. This important aspect has led to the development of the current strategies both for the dissemination and acceptability of the software and looking for funding and opportunities for further development. In 2013, the JRC has been actively deploying an unrolling of events /trainings for implementation and acceptability.

Tool testing and refinements

The FP7 RTD project led to a prototype. This prototype was tested on various stakeholders under the coordination of JRC in 2013. It has been the subject to scrutiny both by experts and by FACET industry group stakeholders that have used the tool on a range of case studies in different areas. This has allowed to test and refine the beta version of the software, in particular for food contact materials which includes a relatively complex module to predict and model migration of substances for materials that can be not only plastics but also others such as paper and board, and in the case of plastics both for monolayers and multilayers.

Trainings

The JRC has been organising dedicated trainings in 2013 to help our stakeholders understand the functioning of the IT tool, to train on its use for dedicated user-based exposure estimations, and to obtain feedback. One aim of the training and extensive testing was to transform the tool from an RTD prototype into a functional widely usable tool facilitating the work of exposure assessment for the 3 sectors of additives, flavourings and food contact materials.

These trainings were conducted with a philosophy of "train the trainers" and have included in 2013:

- | | |
|-------|---|
| 10/09 | Basic training for the packaging value chain stakeholders representing more than 10 industry associations in the field of packaging (ranging from plastics, paper and board, inks, coatings, chemicals, adhesives etc.). The training took place at the European PlasticsConverters -EuPC headquarters. |
| 23/09 | Feedback from FIG on use of FACET |

30/09	Release of version 2.02 of FACET with additional advanced modules
11/10	Basic training additives for additive value chain stakeholders (FoodDrinkEurope headquarters)
05-06/11	Debriefings of DG SANCO for all 3 sectors which took place on November 05 th (Additives, Flavourings) and 06 th (FCM)
06/11	Basic training for flavourings value chain stakeholders (European Flavours Association)
07/11	Advanced training for food contact materials stakeholders users (CEFIC headquarters)
28/10	Release to EFSA (version 2.04)
12-13/11	First familiarisation interactive meeting for staff of the European Food Safety Authority (EFSA) specific to the staff of FIP (Food Ingredients and Packaging) Unit for all 3 sectorial applications (food contact materials, additives, flavourings).
09/12	Public launch and satellite training event within the P&P international conference (version 2.05) http://www.food-contact.com/plastics-and-paper.aspx

These trainings were successfully completed. All gave positive feedback and led to wish lists of further user features to widen the use and user friendliness.

The feedback was extremely positive overall. First-time users learned a lot and thought the software was user friendly; occasional users that had started as self-taught learned more. The feedback from the trainings also gave some suggestions for additional tips. The engagement of participants was notably high due to the interest triggered and a true hands-on experience offered within the training. The value of the software was also discussed in the context of innovation (e.g. new substances, new materials), e.g. what can be possible in an advanced level mode; This gave rise to an interest to pursue with a further training of advanced features where changes in additives or materials composition or substitutions in formulations could be screened from an exposure standpoint, which gives a new edge to the marketability of the product.

They trainings allowed to identify refinements to the software both from a cosmetic and from a functional standpoint and well as to give a dynamic post life and demonstrate the applicability and potential for expansion of the prototype tool developed under the RTD project.

Formation of a sustainability core group

A core steering committee was formed.

A first meeting took place on 06.05.2013 in Brussels in preparation for the 2013 activities and beyond. The meeting highlighted 3 aspects for the FACET post project life:

- 1) Implementation. This taking the form of trainings, both for food contact materials (FCM), additives (ADD) and Flavourings (FLA).
- 2) Acceptability: at FIG level, this would be achieved by the development of test cases or applied cases.
- 3) Sustainability, for which two aspects were found: one in the context of EFSA for exposure assessments, and one in the context of the value chain for innovation (this was particularly

relevant for FCM, but also for ADD in the context of their re-evaluation by EFSA and a corresponding sense check by FoodDrinkEurope (FDE)

The meeting also had a strong focus on implementation and specifically trainings. 3 events of phases were foreseen over 2013-2014:

- 1) Commission/EFSA; Trainings would take place in a first phase in 2013 or early 2014, ideally at EFSA; the trainings will encompass ADD/FLA/FCM, order likely two days (1.5 day -ADD/FLA, 1.5 day FCM)- it could be done unit by unit to make it convenient for staff. Two Units are considered the primary beneficiaries: the Food Ingredient and Packaging Unit (FIP) and the Dietary and Chemical Monitoring (DCM Unit). The first training aimed to take place in mid-November and the other in early 2014.
- 2) Member State Competent Authorities, National Reference Laboratories, Panel members of EFSA (FIP/DCM), National Risk Assessment Institutes and research entities: Trainings would take place in a second phase in 2014, at the JRC. Maximum should be 15-20 per session due to the mix of teaching and hands-on practices.
- 3) Value chain; Trainings would take place in a first phase in 2013 in BXL at the professional associations. This training can occur back to back at the different locations covering respectively the 3 sectors ADD/FLA/FCM,

A prelaunch meeting was organised in Brussels on 13.06.2013 (at FoodDrink Europe headquarters). The objectives of the meeting were to agree on the strategy for the launch of the final version of the software and immediate 2013 activities on training and verification/validation. The meeting focused on status, launch and post launch stakeholders and trainings.

The launch was originally planned for July 2013, but due to the holiday period and following a brain storm, this was moved to later in the year in order to plan the first trainings in September-October prior to full launch and allow 6-8 weeks to generate examples over the summer. Trainers were identified and dates were proposed. The maximum number was set to ca. 20 participants being technical people who should be able to train others- selection to be made by FDE. For the trainings, the planning included the development of examples: out of 10 got FCM, 5 would be completely worked out and two would be the object of full review within a training module. A similar approach would be taken for additives and flavourings.

The proposed composition of the core steering sustainability group was discussed and proposed as follows:

Chair	Michael Knowles
Secretary	Catherine Simoneau
FACET WG leader Additives	J-L Volatier
FACET WG leader Flavourings	Catherine Leclercq
FACET WG leader Food Contact Materials	Laurence Castle
JRC CAT head of Unit	Pilar Aguar
FACET Industry Group	Peter Oldring
Crème Global	Cronan McNamara Cian O'Mahony
DG SANCO (Additives, Flavourings)	Michael Flueh (or Wim de Beuckelaere/Miguel-Angel Granero Rosell)
DG SANCO (Food Contact Materials)	Chantal Brueschy (or Annette Schaefer)
FDE	Beate Kettlitz
FIG	Peter Oldring
EFFA	Benjamin Smith
EFSA	Claudia Heppner Mary Gilsenan

Test of FACET within an exposure assessment

FACET was also included as new pilot tool in the context of EFSA exposure assessment on Bisphenol A (<http://www.efsa.europa.eu/en/consultations/call/130725.pdf>).

Use of FACET data for other databases

The databases of food consumption from FACET were integrated into Expofacts, a project for which the JRC also has the legacy of.

Launch

On 9 December 2013, on the occasion of the Plastics & Paper in Contact with Foodstuffs 2013 PIRA conference, the JRC launched the downloadable tool.

It was combined with a ½ day mini workshop preceding the conference which allowed free participation and industrial stakeholders to understand how the tool works and what it can do.

Availability on the a dedicated web site.

Web address: http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food

Facet tools:

http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food/FACET/the-facet-exposure-tool

Upon sign-up to a community of users, one can download:

- A software to download (upon sign up) – include pre-signing a user license agreement
- A user downloadable manual,
- A downloadable technical guidance

New developments from JRC

In order to maximise the impact of FACET, the prototype (RTD output) has now to be verified and refined to the actual user's recommendations. This important aspect has led to the development of strategies to develop an implementation and acceptability of the prototype.

Improvements under the financing of "Proof of Concept instrument"

The Proof of Concept (POC) Instrument is a JRC financial instrument under the form of a grant and represents a key to support the implementation from a prototype product to a fully functional one for a full function access scale. It is a tool that is intended to maximise the commercial and social impact of JRC's activities. It grants to JRC teams willing to transform research results into a product/process/service suitable for commercialisation or for adoption by non-commercial entities (e.g. Member States authorities, NGOs...). The target is to disseminate, via licensing, research results to stakeholders or industrials in Europe.

The interaction with EFSA allowed to submit a proposal for funding to the Unit of JRC granting this financial POC instrument and the JRC was awarded funding for 2014. Several improvements will be brought to the software and are briefly summarized below:

The data, software and model development work will be carried out by Creme Global, an SME specialising in predictive intake modelling and software which was a partner and work package leader in the project, responsible for developing the databases, exposure models, and software application.

Data Upload Feature

Based on feedback from industry and EFSA, a feature is required that will facilitate the upload of data on chemical occurrence from Microsoft Excel spread sheets. This is because most data management (e.g. monitoring data in member states) is performed with Excel by competent authorities and others. An upload facility to introduce new data for exposure assessment will be developed. In parallel, a set of standardised Excel templates will be developed in collaboration with stakeholders

that can be used for uploading chemical occurrence data to the FACET software. Additionally, the following was deemed necessary for the different chemical areas:

Improvements to Functionality, Workflow and User Interface

Based on user feedback from stakeholders, a number of cosmetics updates will add considerable benefit to the tool and greatly improve its usability (e.g. function to change units in the exposure output, improved labelling on graphical outputs, filter function for large tables to view appropriate data, easier selection of food consumption output in food packaging assessments, inclusion of a record of packaging types selected in a food contact materials' exposure assessment, selection by packaging type, improved formatting of output in automatically generated reports, updating of default outputs for flavourings/additives to reflect changes in legislation (P97.5 -> P95), making 95% confidence interval the default, simplification of fields in inventory list of substances for food contact materials, standardisation of all probabilities in software to a number between 0 and 1 and restriction of ability to enter invalid ranges of probability parameters.

Data Updates

This updates will include for example a list of pack type definitions in software itself for ease of access (as opposed to in separate documentation), a list of reconstituted foods in the software for the users information and updated CAS numbers for particular flavouring substances in the software.

Model Updates

The updates of the model will target -in particular for packaging- how the model runs when considering barrier layers and set-off from substances in inks to the food contact layer and in allowing users to be able link analytical data to the market shares of different pack type descriptions, and to accommodate new uploaded data types.

Documentation

All the relevant documentation will be updated (e.g. Technical Manual, User Manual). Downloadable training manuals specific to sectors with exercises will be produced (e.g Packaging Training Manual, Flavourings Training Manual, Additives Training Manual).

Plan for exploitation

The general response from the pilot trainings run in 2013 was that the FACET tool was user-friendly and useful. The trainings all achieved the objectives set and generated great interest. The feedback was extremely positive overall.

The expected results (software with the new functionalities) have two main market potentials:

Market in a risk assessment context:

The EFSA acceptance which will be improved by the implementation of suggested functionalities is a gateway for further trainings for other Units in EFSA, for panel experts of EFSA, as well as for member states competent authorities, risk assessment and enforcement bodies. This tool has the potential to be of major impact for exposure assessment, as it reduces the uncertainties for the evaluation for these 3 specific sectors which responds to similar yet highly specific pieces of legislation in place (e.g. 1333/2008 and amendments for additives, 1334/2008 and amendments for flavourings and 10/2011 for plastics in contact with foods). This aspect is particularly relevant for specific exposure assessments that can correspond to crisis and therefore heightened sensitivity (e.g. 4-methyl benzophenone in cereals, bisphenol A, etc.). In addition a forward looking use of the tool is to allow to streamline the assessment leading to authorisation of substances by EFSA especially for areas not yet harmonised at the EU level where the approach is still open and should be as fit for purpose as possible with respect to burden and cost/benefit (especially with a long range strategies of developing legislative options fitting better the SANCO roadmap and the REFIT programme).

Innovation and safety by design context

In addition, in the context of innovation FACET can be used as a screening tool to explore changes in the formulations of flavours, additives or food contact substances or of entire layers of polymers (e.g. in multilayer materials) to promote new effective or more sustainable developments. For the industry, the engagement of participants is already notably high due to the interest triggered and a true hands-on experience seen in the trainings. The value of the software was then discussed in the context of innovation (e.g. new substances, new material), e.g. what can be possible in an "advanced level" mode for the software; This gave rise to an interest to pursue these advanced features where changes in materials composition or substitutions in formulations could be screened from an exposure standpoint, which gives a new edge to the marketability of the products.

Proposed exploitation

The exploitation of the tool will also include the formation of a Sustainability and User Committee that will aim to

- 1) maintain the viability of the FACET tool and of the migration model for migrants from packaging for foodstuffs and
- 2) to ensure that updates are undertaken in order to reflect any significant changes in the market place and to incorporate new data where necessary or where highly requested.

This user committee will have members of leaders of the three main work-streams, additives, flavours and packaging, representatives from Commission SANCO –services having the files for Food Contact (E6), Additives, Flavouring (DDG2E3), RTD, EFSA, JRC, FDE (for Additives industry), EFA (for Flavours industry), FIG (=Facet Industry Group, representing the entirety of the value chain of the Packaging Industry), Creme Global, etc.

The JRC will also organise further trainings as follows: Advanced training of EFSA staff (train the trainers), Basic + advanced training of Panels members of EFSA, Trainings of the Member States Competent Authorities, or delegates of the risk assessment or National Reference Laboratories.

The support via the POC instrument will also allow to provide a buffer time zone and opportunity to strategize and seek sources of funding to sustain and expand the tool further downstream (e.g. from industry in the context of innovation, the EU Commission in the context of better food safety exposure tool that can open streamlining of legislative options in the context of REFIT, or EFSA and of the next calls of H2020).

Related documentation available upon sign-up to the FACET community users, accepting the User License Agreement. The manual and technical documents accompany the download of the software. The training manuals and exercises are given in the preparation of the ad-hoc trainings and/or upon request.

Web site: http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food/FACET/the-facet-exposure-tool

1. **FACET 1.9.1 Technical Documentation.pdf**
2. **FACET 1.9.9 Manual.pdf**
3. **10-09-2013 FACET FCM Training Manual.pdf**
4. **10-09-2013 FACET FCM Training Exercises.pdf**
5. **11-10-2013 FACET Additive Training Manual.pdf**
6. **11-10-2013 FACET Additive Training Exercises.pdf**
7. **06-11-2013 FACET Flavouring Training Manual.pdf**
8. **06-11-2013 FACET Flavouring Training Exercises.pdf**

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Abstract

FACET is a model, dynamic tool which was created in recent years and presented in its dedicated public conference in October 2012. The model is developed with the aim to estimate dietary exposure to flavourings, additives and food contact materials substances and compare the results with available safety limits. The tool developed within the FACET project should allow reducing significantly the uncertainty in the level of dietary exposure to additives and flavouring substances in the EU population. JRC was involved from the inception of the project as partner. In addition, JRC is leading the implementation and sustainability of the project via a dedicated group.

The first task is now to promote the uptake of the FACET modelling system, to make users understand the functioning of the IT tool and to use it for own exposure estimations. This report presents the activities carried out in 2013 for the milestones and progress of the dissemination, training and sustainability for the different stakeholders.

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